

PACKAGE LEAFLET: INFORMATION FOR THE USER

FEBRICET

120 mg / 5 ml syrup

PARACETAMOL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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2. Before you take FEBRICET
3. How to take use FEBRICET
4. Possible side effects
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1. WHAT FEBRICET IS AND WHAT IT IS USED FOR

FEBRICET syrup contains paracetamol which is an analgesic (a pain killer that reduces aches and shivers) and antipyretic (it reduces temperature when a child has a fever).

FEBRICET syrup relieves the pain of teething, toothache and sore throats and reduces the fever often associated with colds and 'flu and childhood infections such as chicken pox, whooping cough, measles and mumps.

2. BEFORE YOU TAKE FEBRICET

Do not give FEBRICET to a child

- If the child is allergic (hypersensitive) to Paracetamol or to any of the other ingredients in this medicine (see section 6).
- If the child has a known intolerance to the sugar (fructose)
- With other products containing paracetamol

Take special care with FEBRICET

Tell your doctor if:

- The child suffers from liver or kidney problems.
- The baby was born prematurely and is under 3 months.

Taking other medicines

Please tell your doctor or pharmacist if your baby is taking or has recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor before you give FEBRICET to a child if the child is taking:

- Metoclopramide or domperidone (used to treat nausea and vomiting) or cholestyramine (used to treat high cholesterol).
- Warfarin or other drugs used to prevent blood clotting.

Effects of paracetamol on laboratory tests

Uric acid and blood sugar tests may be affected.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant see your doctor before you take FEBRICET.

You can take this product whilst breastfeeding.

Important information about some of the ingredients of FEBRICET

If your child has intolerance to some sugars, contact your doctor since this medicine contains sucrose.

3. HOW TO TAKE FEBRICET

Always take FEBRICET exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

Check the tables below to see how much of the medicine to use.

- For oral use only.
- It is important to shake the bottle for at least 10 seconds before use.
- Never give more medicine than shown in the table.
- Always use the spoon supplied with the pack.
- Do not overfill the spoon.
- Do not give with any other paracetamol-containing products.

Age: 2 – 3 months		Dose
1. Post-vaccination fever		one 2.5 mL measure
2. Other causes of Pain and Fever only if • Weighs over 4 kg • Born after 37 weeks		One 2.5 mL measure If necessary, after 4-6 hours, give a second 2.5 mL dose
• Do not give to babies less than 2 months of age. • Do not give more than 2 doses. • Leave at least 4 hours between doses. • If further doses are needed, talk to your doctor or pharmacist.		
Childs age	How much	How often
3-6 months	One 2.5 mL measure	4 times
6-24 months	One 5 mL spoonful	4 times
2-4 years	One 5 mL spoonful and one 2.5 mL measure	4 times
4-8 years	Two 5 mL spoonfuls	4 times
8-10 years	Three 5 mL spoonfuls	4 times
10-12 years	Four 5 mL spoonfuls	4 times
• Do not give more than 4 doses in any 24 hour period. • Leave at least 4 hours between doses. • Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.		

Not recommended for babies under 2 months except under medical advice.

Do not exceed stated dose.

If symptoms do not improve within 24 hours consult your doctor.

Prolonged use except under medical supervision may be harmful.

This product should only be used when clearly necessary.

If you take more FEBRICET than you should

Immediate medical advice should be sought in the event of overdose because of the risk of irreversible liver damage.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using this medicine and tell your doctor immediately if:

Very rare (affects less than 1 in 10,000 people)

- the child experiences allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- the child experiences a skin rash or peeling, or mouth ulcers.
- the child has previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experiences a similar reaction with this product.
- the child experiences unexpected bruising or bleeding.
- the child experiences changes in blood tests that measure the function of their liver.

Other side effects may include a severe reduction in white blood cells which makes infections more likely.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FEBRICET

Keep out of the reach and sight of children.

Do not store above 25 °C.

Expiration date:

3 (three) years

Do not use this medicine after the expiry date (EXP) shown on the carton and bottle label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**What FEBRICET contains**

The active substance is paracetamol.

5 ml of syrup contains 120 mg of paracetamol.

The other ingredients are:

Propylene glycol, sucrose, methylcellulose 15Mpa, hydroxyethyl cellulose 5500 mPa, 96% ethanol, potassium sorbate, sodium saccharin dihydrate, citric acid monohydrate, cherry flavor 11035-33, purified water.

What FEBRICET looks like and contents of the pack

FEBRICET 120 mg / 5 ml syrup

Dark glass bottles, hydrolytic resistance type III with polyethylene cap.

One teaspoon (5 ml) of syrup contains 120 mg of paracetamol.

Syrup (a clear, colorless solution, specific cherry taste and smell).

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Hemofarm d.o.o. Banja Luka

Novakovići bb, Banja Luka, BiH

Manufacturer of the medicinal product

Hemofarm d.o.o. Banja Luka

Novakovići bb, Banja Luka, BiH